7.0 A - RESEARCH PROTOCOL FORMAT AND REQUIREMENTS (OSIRIS SUBMISSIONS)

OSIRIS is a web-based application that was created to improve human subject protections and to enable the IRB to better serve the research community. The application is based on the use of a question and answer format using "smart forms." Based on responses to specific questions, the system may branch to additional questions which must be addressed. Information about OSIRIS can be accessed at: http://www.irb.pitt.edu/OSIRIS/osiris.htm.

When preparing a protocol through OSIRIS, each question should be answered carefully and completely. Failure to do so may result in delays in the review of the protocol. Help text, available at the right side of each screen, provides important information that may aid in the appropriate preparation of the protocol.

Triage and Cover Sheet

The Triage Section (T1.0 – T3.0) determines the type of IRB review necessary. The fully completed Cover Sheet Section (CS1.0 – CS16.0) accompanies each OSIRIS submission.

Reason for Submission, Study Title and Abstract (CS1.0 - CS2.0)

A reason for the submission must be selected. In addition, a brief abstract of the proposed research study must be provided that summarizes its specific aims, experimental design, methods, and subject population.

PI, Co- I and Staff Information (CS3.0 – CS5.0)

The *Select* button should be used to choose the Principal Investigator from the drop down list. Inclusion on the list requires completion of specific training modules offered through the Internet-based Studies in Education and Research (ISER) modules [http://cme.hs.pitt.edu]. The Research Integrity module must be completed along with Human Subjects Research in Biomedical Science OR Human Subjects Research in Social Behavioral Science. These modules must be completed by investigators and their study team. Without the required training, investigators and study staff are unable to be associated with the electronic study that will be sent to the IRB for review. Investigators who do not have faculty appointments (regular or adjunct) or other direct relationship with the University must demonstrate completion of an equivalent educational program on the protection of human research participants (i.e. they are not required to complete the University's computer based training but may do so if they do not have access to a similar program). In this scenario, the investigator of the study will have to contact the OSIRIS team in order to have the person's name added into the system before s/he can be selected as part of the research team.

Clinical and Translational Research Center (CTRC) and Scientific Review (CS7.0 - CS8.0)[1]

A protocol that is designed to utilize the services of a CTRC will be prompted by OSIRIS for completion of the CTRC forms. The CTRC will have access to the information.

[1] All requests for Ancillary Reviews are disseminated to the appropriate department through OSIRIS and must be completed prior to IRB review. The system does not allow the IRB to review the protocol prior to the approval of the appropriate Ancillary Reviews.

All research protocols that require local scientific review prior to their submission for initial IRB approval will be forwarded for scientific review.

Investigational Drug, IND and IDE (CS9.0 - CS10.0)

1) Investigational New Drug (IND) Number: The IND number corresponding to the FDA accepted IND application must be designated if the research study involves the evaluation or use of an unapproved drug substance (i.e., drug, chemical, biological). See Section 2.1 in OSIRIS for additional information.

2) Investigational Device Exemption (IDE) #: If the device or its use poses greater than non-significant risk or the IRB questions the non-significant risk classification of the device study, a FDA-approved IDE is required prior to review and approval of the research protocol by the IRB. However, if the principal investigator considers the research of an unapproved device to be of non-significant risk, s/he should submit a justification in Section 2.2 of OSIRIS: Evaluation of a Device for Safety/Effectiveness. If the IRB approves the research study of the unapproved device as constituting a non-significant risk, subsequent IRB review and approval of the research protocol can proceed without further involvement of the FDA. (See Appendix F of the IRB Reference Manual, Investigational Devices.)

Sponsor Protocol and Brochure (CS11.0)

If the study is funded by a commercial (industry) sponsor, the sponsor protocol and brochure should be uploaded.

Fee Schedule

An IRB fee for initial and continuing (renewal) review of the research is required. The fee structure is as follows:

New Exempt or Expedited Study	$500
New Full Board Study	$1500
Renewal of Expedited Study	$250
Renewal of Full Board Study	$500

Fees can be submitted in the form of a check made out to the University of Pittsburgh or on an industry sponsored fee form (www.irb.pitt.edu). In addition, a waiver of the fee can be requested through a written memo attached to the IRB submission.

The OSIRIS system will forward information to the appropriate ancillary review committees based on the information provided in the OSIRIS application. This occurs prior to the initiation of IRB review.

Radiation Safety, Biosafety and Fiscal Review Approval (CS12.0 – CS13.0)

The Human Use Subcommittee, Radiation Safety Committee (HUSC), must approve experimental interventions involving human subject exposure to ionizing radiation. HUSC approval is not required for routine diagnostic procedures performed for screening or monitoring/followup purposes. Refer to Appendix D of the IRB Reference Manual for the Use of Human Subjects in Research for HUSC submission requirements and information on standard statements to address radiation risks.

The Institutional Biosafety (recombinant DNA) Committee (IBC-rDNA) must approve any research study involving the deliberate transfer of rDNA, or DNA or RNA derived from rDNA into one or more human research subjects.

UPMC Research Fiscal Review is required if research related activities are performed within any UPMC facility. The IRB and/or UPMC have the authority to require Fiscal review and approval at any time during the conduct of this research study.

Clinical Trials Office (CS14.1)

All applicable industry-initiated and sponsored clinical trials (conducted within the UPMC environment) must be processed by the UPMC Clinical Trials Office (CTO). Refer to the OSIRIS Help Text to determine if a protocol is eligible to utilize the CTO.

The University of Pittsburgh IRB can not serve as the IRB of record for any studies that are processed through the UPMC Clinical Trials Office (please see the schematic of UPMC CTO processing procedures at http://www.irb.pitt.edu/CTO/ for additional information).

Study Site(s) Information Special Research Subject Population(s) (CS15.0 - CS16.0)

In this section, all sites should be selected where the research procedures will be performed for the purposes of the study; this includes the informed consent process. The appropriate subject population for inclusion in the study should also be addressed in this section. For federally funded studies all institutions engaged in research must have a valid FWA.

Section 1 – Objective, Aims, and Background and Significance (1.1-1.4)

The overall purpose of the research study should be addressed in this section. When completing this section, a concise and realistic description of the goals or aims of the study should be provided as well as a description of the questions or hypotheses that will be addressed.

A summary of the background to the research proposal should be provided including a discussion of previous and/or preliminary relevant studies. In addressing this section, the investigator should summarize existing knowledge of the field and specifically identify the gaps that the proposed research is intended to fill. This should include a concise statement of the importance of the proposed research by relating the specific aims to longer-term objectives. Please provide enough detail for the IRB to assess the scientific merit of the research.

For research studies involving the evaluation of a drug, a summary of the results of prior clinical studies (or in the absence of prior clinical studies, prior animal studies) which suggest that the drug may be safe and effective for the specific indication under investigation (should be provided). In addition, the drug dosages and duration of dosing evaluated in prior clinical (or preclinical) studies should be described and related to the drug dosages and duration of dosing being proposed in the current research study.

Section 2 – Research Design and Methods (2.1 – 2.21)

Section 2 consists of branching questions related to the conduct of the study. Investigators may be prompted to answer any or all of the questions in the following sections based on the information that is entered. Questions in this section include, but are not limited to, the following:

- Evaluation of Drug, Biological or Dietary Supplement
- Evaluation of Device for Safety/Effectiveness (Full Board),
- Classification and Methodological Design
- Subject Withdrawal from Effective Therapy
- Screening Procedures
- Experimental Interventions
- Follow Up Procedures
- Non-Standard Questionnaires or Survey Instruments
- Routine Medical Care
- Blood Samples
- Total Duration of Subject's Participation
- Planned Deception
- Honest Broker for De-Identification
- HIPAA and Identifiable Record Information
- Collection and Banking of Tissue or Biological Specimens
- Information on Family or Acquaintances
- Endpoints or outcomes
- Statistical Analysis
- Foreign Country or Site Different from Pittsburgh
- Investigators at External Sites Directed by PI
- Study Involves PA Nursing Homes

Section 2.1 - FDA Regulated Research

All drug substances being used or evaluated in a research study must be either FDA approved for marketing or must be the subject of a FDA-approved Investigational New Drug (IND) exemption. This requirement applies to research involving unapproved drug substances which are being used to induce or measure a physiological effect as well as research directed at evaluating the safety and effectiveness of drug substances for the treatment, diagnosis, prevention or mitigation of specific diseases or conditions. [Note: Dependent upon prevailing FDA policies, there may be exceptions to this requirement (e.g., minimally manipulated bone marrow transplants, stable isotope derivatives of normal body substrates). When uncertainty exists, contact the appropriate FDA review division, or the IRB office. The University of Pittsburgh Office for Investigator-Sponsored IND and IDE Support (O3IS) can assist with Investigator initiated requests.

Research involving the "off-label" use of FDA-approved drugs also requires an IND if any one of the following three conditions exists:

a. The research is intended to be reported to the FDA in support of a new labeling indication for the drug or to support any other significant change in the labeling of the drug; or

b. The research is intended to support a significant change in the advertising for the drug; or

c. The research involves a route of administration or dosage level, use in a subject population, or other factor that significantly increases (i.e., compared to the FDA-approved indication for use of the drug) the risks (or decreases the acceptability of the risks) associated with the use of the drug.

For nutritional supplements, current FDA policies require the submission of an IND if the research study involves the evaluation of the supplement for the treatment of a specific disease or condition. If uncertainty

exists, the investigator should contact the University of Pittsburgh Office for Investigator-Sponsored IND and IDE Support (O3IS), the FDA or the IRB Office.

Placebo Controlled Studies (2.3 - 2.4)

For research studies that involve a placebo-control arm, the investigator must address if there is an approved diagnostic/treatment approach that is currently recognized as being effective for the proposed subjects' disease or condition that is being withheld from subjects assigned to the placebo arm of the study. Investigators are prompted to address a variety of questions to justify the use of the placebo. The investigator should answer with enough detail to allow the IRB to assess the risk/benefit ratio of such an approach.

Study Procedures / Interventions (2.6)

In this section, the investigator should list, in sequential order, the study procedures that will be performed specifically for the purpose of this research study; including, but not limited to:

- the dosages, routes of administration, FDA approval status, and dosing duration of all drugs being evaluated in the research study
- procedures (e.g., device placement and testing, duration of exposure, number of exposures) associated with the research evaluation of a device
- psychological or behavioral interventions or procedures
- the type, number, and volume of biological sample collections
- a description of all tests, questionnaires, surveys, interviews, etc., which the subject will be requested to complete; the number of times each assessment will be administered; and the estimated time required for each visit
- the nature and number of audio or video recordings (including photographs) that will be made; and a description of how and where the recordings will be used

Clinical procedures that are being performed for the proposed subjects' routine medical care should NOT be listed.

Total Duration of Subject's Participation (2.11)

The duration of participation of individual subjects in the research study should be specified, e.g. "one hour" for a single session experimental study; "five years' for a multi phase clinical study where the study intervention and follow-up occurs over five years. Care should be taken to ensure that the specified duration of participation of individual subjects in the research study is in agreement with the procedures in OSIRIS Section 2.6.

Collection and Banking of Tissue or Biological Specimens (2.15)

If linkage codes will be utilized to protect subject confidentiality this should be indicated along with a description of the plans for the physical security of the information linking these codes to the subjects' identities. Throughout the section, if applicable, the investigator should address 1) how confidentiality will be maintained for specimens sent to external laboratories for analysis; and 2) whether a Federal Certificate of Confidentiality will be obtained for this research activity.

Please refer to Appendix E of the IRB Reference Manual for additional information regarding the use and storage of biological specimens.

Information on Family or Acquaintances (2.16)

If this research includes a medical or pedigree history with collection of private information about the family members of research subjects, please refer to Appendix M of the IRB Reference Manual.

Endpoints, Statistical Analysis (2.17-2.18)

Include in this section a summary of how the data will be collected and analyzed statistically (in general terms).

Foreign Country or Site Different from Pittsburgh (2.19)

If research is being conducted at foreign sites, OSIRIS prompts investigators to provide information about the research. The Office for Human Research Protections has developed an International Compilation of Human Subject Research Protections. The Compilation lists the laws, regulations, and guidelines of over 50 countries where DHHS funded or supported research is conducted.

The Compilation provides direct web links to each country's Key Organizations and laws, whenever available. This Compilation should assist in meeting regulatory requirements to assure that research studies comply with applicable law.

The Compilation can be accessed on the OHRP web site: http://www.hhs.gov/ohrp/international/HSPCompilation.pdf. To use the Compilation, go to page 5 and then click on the country of interest.

Section 3 – Human Subjects (3.1 – 3.15)

Participation of Children (3.5)

If children are to be included in the research study the following should be provided: 1) the rationale for the specific age ranges of children to be included; 2) a description of the expertise of the investigative team for dealing with children of the specified age ranges; 3) a description of the adequacy of the research facilities to accommodate children of the specified age ranges; 4) information about inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

In addition, the investigator must provide an appropriate rationale for how the proposed research satisfies one of the regulatory criteria 45 CFR 46.404, 45 CFR 405, 45 CFR 406 and 45 CFR 407.

Participation of Prisoners (3.6)

"Prisoner" means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide

alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

Please refer to Chapter 6 of the IRB Reference Manual for further information about research involving prisoners.

Participation of Pregnant Women, Involvement of Neonates, (3.7 – 3.8)

The Federal Policy and FDA regulations governing human subject protections specify that for research involving pregnant women and/or fetuses, in situ, or neonates of uncertain viability or nonviable neonates must conform to each of the outlined general requirements. Please refer to Chapter 6 of the IRB Reference Manual for further information about research involving pregnant women, or neonates.

Involvement of Fetal Tissues or Organs (3.9)

In accordance with the Pennsylvania Abortion Control Act, fetal tissues or organs may only be obtained for use in research subsequent to obtaining the written informed consent (i.e., for use of the fetal tissue in research) of the mother. The Pennsylvania Abortion Control Act specifies that research involving the use of fetal tissue or organs must also conform to each of the following general requirements:

- informed consent for the research use of fetal tissue derived from an abortion will be obtained separate from, and after, the decision and consent to abort has been made
- no consideration of any kind (i.e., monetary or otherwise) will be offered to the mother in obtaining her consent for the research use of the fetal tissue or organs
- the mother will not be permitted to designate a recipient of the fetal tissue or organs for use in research
- all persons who participate in the procurement or use of the fetal tissue or organs will be informed as to the source of the tissue (e.g., abortion, miscarriage, stillbirth, ectopic pregnancy)

Inclusion/Exclusion Criteria (3.13-3.15)

When addressing this section, the investigator should:

1) List the specific criteria for the inclusion of potential subjects in, or the exclusion of potential subjects from, the research study. Where applicable, the acceptable range of biological values must be provided.

   Note: In general, any modification of the inclusion or exclusion criteria to relax (i.e., broaden inclusion criteria, narrow exclusion criteria) study entry requirements will require full board review and approval. This should be taken into consideration during initial study design.
2) If females of childbearing potential are included in the research study and if procedures are used that may be harmful to a fetus, the investigator should identify the precautions that will be taken to assure the participant is not pregnant. (See section 8.2, Sample Informed Consent statement.) (Reference the Guidance for Reproductive Risk Language for Consents)

3) If interventions (e.g., drugs or devices) are used in the research that may be associated with reproductive risks, precautions (e.g., contraception measures for both male and female participants) to

be taken to assure appropriate protections should be outlined. (See section 8.2, Sample Informed Consent statement.)

4) If HIV serostatus will be evaluated specifically for the purpose of participation in this research study, provide a rationale for this testing.

   Note: There must be a separate informed consent document for HIV testing which addresses specific issues such as the availability of counseling before and after the decision to participate in such testing, the required provision of test results to the subject, and how confidentiality of test results will be maintained. See example of informed consent for HIV testing under Appendix H of the Reference Manual.

Section 4 – Recruitment and Informed Consent Procedures (4.1 – 4.14)

Use of Advertisements (4.1)

All advertisements directed at potential research subjects must be approved by the IRB prior to their use. Advertisements developed in the future must be submitted as a modification to a currently approved research study. Any advertisement used for subject recruitment should be attached to the OSIRIS submission. (See Chapter 5 for advertisement requirements).

Other Methods for Identifying Subjects, Initial Contact (4.4-4.5)

In addition to providing advertisements to the IRB, the investigator must also: Address the method by which research subjects will be initially contacted to ascertain their interest in research participation. Note that the University IRB prohibits “cold-calling” of potential research subjects. “Cold-calling” is the practice of investigators or research staff, who are unknown to the potential research subjects, initiating contact with the potential subjects based on their prior knowledge of confidential (e.g., medical record) information. See Chapter 5 for more information.

In addition, the following issues must be addressed:

- The methods used to identify potential subjects
- A description of how potential subjects will be initially contacted and the study described. (This may be accomplished by attaching a copy of the recruitment letter or telephone script.)

Waiver of Signed Informed Consent (4.6)

If requesting a waiver of the requirement to document informed consent (i.e., to obtain a signed informed consent document), the investigator must address and justify each of the criteria for such a waiver as outlined under Section 8.3.2 of the IRB Reference Manual. In addition, the investigator should also provide a script of the information that will be provided in obtaining the potential subject’s consent for study participation.

Waiver of Informed Consent for Minimal Risk (Full Board) (4.7)

If requesting a waiver of the requirements for obtaining informed consent, the investigator must address and justify each of the criteria for such a waiver as outlined under Section 8.3.1 of the IRB Reference Manual.

Exception of the Requirement to Obtain Informed Consent for Emergency Research (4.8)

The Federal Policy and FDA regulations permit individuals to be enrolled, without their legally effective informed consent (or the consent of their authorized representative) in research studies directed at the evaluation of emergency care interventions provided that certain basic conditions are met. Please refer to Chapter 8, Section 8.3.3 of the IRB Reference Manual for further information.

Informed Consent Forms (4.9)

No investigator may involve an individual in a research study unless the investigator has obtained prospectively the legally effective, written informed consent of the individual or the individual's legally authorized representative unless the IRB has granted exempt status to the research study or has specifically waived the requirement for written informed consent. Note that verbal or telephone consent is not acceptable unless the IRB has specifically waived the requirement for a signed consent form.

Please refer to Chapter 8 of the IRB Reference Manual for complete information regarding the informed consent process and informed consent document. Informed consent documents must be uploaded into OSIRIS in Microsoft Word with the required watermark added as a footer to each page.

Adult Subjects Capable of Providing Consent (4.10)

All adults, regardless of their diagnosis or condition, should be presumed competent to provide consent unless there is evidence of serious mental disability that would impair reasoning or judgement. If proxy consent is planned, the following must be included in the submission:

- the rationale for the need to obtain proxy consent
- the specific criteria that will be used in determining whether a potential subject is "incapacitated" (i.e., unable to provide direct consent)
- the criteria for who will be approached and in what order to provide proxy consent
- if and under what circumstances the "assent" of the mentally incapacitated subject will be obtained for study participation and
- in the consent form under Voluntary Consent, include a signature line for the research subject to provide their written informed consent to continue participation in the study should they become competent to provide direct consent

Point When Informed Consent Will Be Obtained and Informing Subjects (4.11 – 4.13)

In this section of OSIRIS, the investigator must:

1. Address at what time informed consent would be obtained

2. Describe the process that will be utilized to ensure that potential subjects are fully informed of nature of the research, the risks and potential benefits of study participation, and their rights as a research subject prior to their obtaining their signature on the informed consent document.
3. Identify and justify (i.e., by name and/or position) who will be responsible for obtaining informed consent of the subject,

Section 5 – Potential Risks and Benefits (5.1 – 5.6)

In addressing this section of OSIRIS, the investigator should provide a description of:

1. Any potential risks (physical, psychological, social, legal, economic or other) associated with research study participation (including screening procedures, experimental intervention, and follow-up/monitoring procedures performed specifically for the purpose of the research study) and an assessment of their likelihood and severity.

2. The procedures for protecting against or minimizing any potential risks.
    - Examples of ways to minimize risk include:
        - Alternatives: other procedures that are less risky
        - Precautions: procedures to decrease the likelihood that harms will occur
        - Safeguards: procedures to deal with harms if they occur

3. How potential adverse events will be detected and handled. This may include a description of follow-up procedures, instructions provided to study participants should any problems arise, as well as the adequacies of the staff and facilities which are available to handle adverse events.

Endpoints for Subject Discontinuation (5.7)

This section should be addressed by describing under what circumstances the principal investigator will terminate the research study or the involvement of a given subject in the research study.

Individuals Permitted to Access Study Data/Documents, Confidentiality, Handling of Data Upon Withdrawal (5.8 – 5.11)

This section should be addressed by describing the specific steps that will be taken (i.e., during study participation, after study participation, and with the publication of study results) to ensure that the subject's participation in the research study and respective data will be kept confidential.

Potential Benefits of Study Participation (5.12)

When completing this section the investigator should address the potential benefits (i.e., to the subject or society) of research study participation.

- Where there are no potential direct benefits to research subjects, this should be explicitly stated.
- If subjects may potentially derive direct benefit from study participation, a description of such benefits should be outlined. If all, or only certain of the research subjects may derive such direct benefit from study participation, this should be described.

- The potential benefits (e.g., increased knowledge, improved safety, better health, technological advancement) to society that may result from the conduct of the research study should be included.
- Note: payment or other remuneration to a research subject is not a benefit of study participation; it is a recruitment incentive. Payment or other remuneration should not be stated as a benefit. Such information should be placed in the Costs and Payments section (see section 6.2)

Data and Safety Monitoring Plan (5.13)

This section specifically asks for a description of the study design safeguards. The PI should include a description of the steps to safeguard the data and confidentiality of the subjects. The PI should include a description of the plan of the research team to regularly evaluate recruitment, adverse events, protocol adherence, modifications, risks, and unanticipated problems associated with the research. See Appendix L of the IRB Reference Manual regarding Data and Safety Monitoring Plans.

Section 6 – Costs and Payments

Subjects or Insurance Providers Charged for Procedures (6.1)

In this section, the investigator should specify if research subjects or their insurance providers will be charged for any of the procedures (i.e., screening procedures, experimental interventions, follow-up/monitoring procedures) performed for the purpose of this research study.

Charging Research Subjects for Investigational Drugs and Devices:
Under the IND and IDE regulations, the FDA will permit a sponsor to charge investigators for an investigational drug or device used in a clinical trial or treatment protocol. The FDA specifies, however, that the charge should not exceed an amount that is necessary to recover the costs associated with the manufacture, research, development, and handling of the investigational new drug or device. Such charges must be authorized prospectively by the FDA.

The FDA permits the investigator to pass sponsor charges for investigational new drugs and devices to research subjects participating in corresponding clinical trials or treatment protocols. The decision to pass such charges to research subjects should be based on the subject realizing a potential benefit from study participation. If subjects will be charged for the investigational (IND, IDE) drug or device, the investigator should provide assurance that the FDA has given approval for the sponsor of this research study to charge investigators for the investigational drug or device. For an investigational device, the investigator should indicate if the Health Care Financing Administration has designated it as a Class B medical device.

Subjects Remunerated for Participation (6.2)

1. Payments or other remuneration to the research subject must be clearly stated. Payments/remuneration may not be so large as to become coercive.
2. The disbursement schedule for payments/remuneration and/or the terms under which partial payment/remuneration will be made must be clearly disclosed. The amounts and terms of payment or other remuneration for partial completion of the research study should not be such that they are

coercive to the subject's continued participation in the research study should s/he wish to withdraw from participation

Section 7 – Qualifications and Source(s) of Support

Qualifications and Experience (7.1)

A brief summary of the principal investigator's and listed co-investigators' qualifications and experience as related to the proposed research study should be provided.

1. Do not submit curriculum vitae or biographical sketches.
2. Principal investigators who are not faculty of the University or staff of an institution for which the IRB is the IRB-of-Record (e.g., students) must be sponsored by a University faculty member who is also listed as a co-investigator on the research protocol. A respective letter of support signed by the sponsoring faculty member shall be included under the IRB Cover Sheet.
3. Research studies involving human subjects and patients must include the involvement of co-investigators who possess the appropriate expertise for the procedures proposed (e.g., a physician for drug administration procedures; a surgeon for surgical procedures; a radiologist for diagnostic imaging procedures, pediatric specialists/investigators for studies involving children, etc.).

All Sources of Support (7.2)

1. All applicable sources of support for the research study should be checked and the corresponding sponsor should be specified.
2. If the study is federally funded, the responsible federal agency, grant number (if known at the time of IRB submission) and awardee institution should be specified.
    - If the study is federally funded and the University of Pittsburgh is the grantee institution, a copy of the entire grant application (with salary information redacted) must be uploaded with the submission.

Financial or Equity Interests (7.3)

1. This section is used by the IRB to determine if the principal investigator or any co-investigators may have a potential financial conflict-of-interest in the sponsor of the research or the technology being evaluated. The Conflict of Interest Committee's Human Subject Research Policy can be found at http://www.coi.pitt.edu/Policies/IRBCOIPolicy.htm .